

REMARKS

Applicants respectfully request entry and consideration of the following commentary upon continued examination of the present application.

Rejection of Claim under 35 USC § 103(a)

The Examiner withdrew all anticipation rejections while maintaining a rejection of claims 1, 3-9 and 11-14 for alleged obviousness over WO 01/41768 to Meijer in view of U.S. published application 2004/0019015 to Nicotera et al. and U.S. patent No. 6,096,873 to Schaefer et al.

Applicants respectfully traverse the rejection.

The Examiner is heard to contend that the Meijer PCT publication, by teaching the use of hymenialdine in treating “neurodegenerative” diseases, somehow would have directed the skilled artisan in a direction whereby “the *inherent effects* of that [prior-art] treatment (inducing cell differentiation) *would ... be carried out* as well” (emphasis added). Applicants respectfully disagree.

As disclosed by Meijer, exemplary neurodegenerative diseases include Alzheimer’s disease, Parkinson’s disease, and multiple system atrophy (page 3, last full paragraph). By contrast, Applicants’ invention is directed to the treatment of “deafness in a subject” (claim 1).

By any conventional definition, the category of “neurodegenerative diseases” does not equate (*i.e.*, is not *coextensive*) with the condition of “deafness.” Thus, it would have been a matter of pure coincidence that a neurodegenerative-disease patient, treated in the manner taught by Meijer PCT, also suffered from deafness and, hence, would experience what the Examiner calls “inherent effects” *vis-à-vis* induction of supernumerary hair cells and Deiters’ cells, as presently recited.

As a matter of law, “inherency” has no place in a sustainable analysis under Section 103. Even were the law otherwise, moreover, the fact would remain that the skilled artisan, informed

by the prior art of record, would never have thought it feasible, let alone well-conceived therapeutically, to apply a treatment that prevents cell death in a neurodegenerative context (Meijer PCT) against the condition of deafness, which is not necessarily associated (and, indeed, is usually not associated) with cell death.

On this last point, Applicants note the Examiner's reliance on Schaefer for the proposition that nerve deafness, *per se*, is considered a "neurodegenerative" disorder. Yet even if it is assumed, *arguendo*, that the population of deaf subjects overlaps that of patients who suffer from a neurodegenerative disorder, the skilled artisan still would not have considered treatment of the latter group to generalize, with reasonable *a priori* predictability, to the former group. There is no evidence whatsoever that efficacy for a given treatment of a neurodegenerative disease is predictive of efficacy in treating deafness. Beyond the fact that it isn't necessarily the case, therefore, it also is decidedly not obvious that teachings of Meijer and Schaefer implicated treating deafness in a subject, as presently claimed.

Perhaps in recognition of this fact, the Examiner cites Nicotera as evidence that "the skilled artisan [would have] a reasonable expectation of success in applying the method of Meijer to treat deafness." Advisory Action, page 2, fifth paragraph. As previously submitted, however, Nicotera describes using a different type of kinase inhibitor, tyrosine kinase inhibitor, to treat deafness. Because the primary reference says nothing about treating deafness, and because Nicotera relates to a different type of kinase inhibitor, the skilled artisan would not have been motivated to combine the teachings of Nicotera and Meijer, as the Examiner contends.

Accordingly, the claimed invention is not obvious over the cited art. Applicants respectfully request withdrawal of the rejection under section 103.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner

is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, Applicants hereby petition for such extension under 37 CFR §1.136 and authorize payment of the related fee(s) from the deposit account.

Respectfully submitted,

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